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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,043	08/28/2006	Dawn Elizabeth Coates	JAMES109.002APC	2754
20995 7590 11/21/2008 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER TSAY, MARSHA M	
			ART UNIT 1656	PAPER NUMBER
			NOTIFICATION DATE 11/21/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/555,043	Applicant(s) COATES ET AL.	
	Examiner Marsha M. Tsay	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,9 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,9 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1656

This Office action is in response to Applicants' remarks received October 24, 2008.

Newly submitted claims 19-20 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 19-20 are drawn to patentably distinct methods of treatment, i.e. a method of inducing proliferation of endothelial cells (claim 19) and a method of inducing angiogenesis in a subject (claim 20).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 19-20 are withdrawn from consideration as being directed to a inventions that are patentably distinct than the originally presented invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 7-8, 10-17 are canceled. Claims 19-20 are withdrawn. Claims 1-6, 9, 18 are currently under examination.

Priority: The request for priority to NEW ZEALAND 526157, filed May 27, 2003, is acknowledged.

Objections and Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1656

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Weng et al. (2001 Acta Pharmaceutica Sinica 36(11): 817-820; IDS 09.13.07). Weng et al. teach velvet antler polypeptides (TVAP) accelerated skin wound healing by stimulating proliferation of epidermal cells (p. 1 of translation). Weng et al. teach an ointment containing 0.8 and 3.2 mg TVAP/g body weight accelerated healing of a rat back skin wound (p. 1-2; claims 1-3, 6, 9). Weng et al. teach 16 and 4 mg TVAP was added into 5 g of an ointment base made of sheep wool lotion, vaseline, and water (p. 2; claims 4-5). Weng et al. further teach the TVAP ointment was applied topically on the wound of the rat every other day at a dose of 50 mg/time/rat within 20 days (p. 2; claims 4-5).

In their remarks, Applicants assert that the Weng et al. reference teaches that total velvet antler polypeptides (TVAP) accelerated skin wound healing by stimulating proliferation of epidermal cells. However, proliferation of epidermal cells, as taught by Weng et al. do not mean that the proliferation of endothelial cells is affected, as claimed. Nothing disclosed in Weng et al. suggests that TVAP will induce proliferation of endothelial cells and/or promote angiogenesis. Therefore, the cited reference discloses an extract that can promote proliferation of epidermal cells, cartilage cells, and fibroblasts. There is no disclosure in the cited reference that this extract has any effect on endothelial cell proliferation or promotion of angiogenesis. Applicant's arguments have been fully considered but they are not persuasive.

Art Unit: 1656

Firstly, it should be noted that statements of inherent properties, intended use, or purpose are not limiting to the interpretation of claims. Therefore, the claims are just directed to an extract of deer velvet proteins which have a molecular weight less than or equal to 10 kDa. The limitation of inducing proliferation of endothelial cells and/or promote angiogenesis is an inherent property of deer velvet proteins which have a molecular weight less than or equal to 10 kDa. Further, it is known in the art that endothelial cells are specialized epithelial cells that line cavities and structures throughout the body (NCBI reference sheets). Therefore, one of ordinary skill would recognize that the TVAP of Weng et al. should also induce proliferation of endothelial cells (which are specialized epithelial cells) since Weng et al. disclose the TVAP induces proliferation of epidermal cells (which are differentiated from epithelial cells).

For at these reasons, the 35 U.S.C. 102(b) rejection is maintained.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weng et al. (2001 Acta Pharmaceutica Sinica 36(11): 817-820; IDS 09.13.07) in view of Schultz (US 20030203001). The teachings of Weng et al. are outlined above. Weng et al. do not teach a growth factor.

Schultz teaches that epidermal growth factors can aid in the wound healing process (p. 1).

Art Unit: 1656

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the velvet antler polypeptides of Weng et al. with the epidermal growth factor of Schultz in order to formulate a third composition that can be applied for the treatment of wounds (claim 18). As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in the prior art."

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Applicant is advised that should claims 1, 2, 4, 6, 9 be found allowable, claims 3, 5 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Art Unit: 1656

In their remarks, Applicants assert claim 3 distinguishes over claims 1 and 2 since claims 1 and 2 do not contain the limitation of the components having been subjected to at least one of the processes recited in claim 3. In relation to claim 5, it would be well known to a person skilled in the art that persistent wounds are a specific subclass of wounds and thus are not identical to the general class of wounds covered by claim 4. Applicant's arguments have been fully considered but they are not persuasive.

Claim 3 is still drawn to an isolated extract of deer velvet, regardless of the method of preparation. The scope of claim 4 still encompasses claim 5 since a persistent wound is just a wound.

For at least these reasons, the objection to having duplicate claims is maintained.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1656

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

November 17, 2008